



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Northeast Region

APR 20 1994

DEPARTMENT OF HEALTH & HUMAN SERVICES
NORHEAST REGION

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April 13, 1994

Mr. Harold C. Winters
Director
Bureau of Marine Development
State House, Station 21
Augusta, ME 04333

Dear Mr. Winters:

Enclosed is the trip report which describes the findings of the evaluation of the growing area survey and classification portion of the Maine Shellfish Sanitation Program. The items found which do not meet the satisfactory compliance requirements of the National Shellfish Sanitation Program are identified on the worksheets for each growing area. They have been extracted and tabulated by area on the trip report attachment Summary of Cited Deficiencies by Area.

In accordance with the FDA Molluscan Shellfish Compliance Program (FOCUS '94), you are advised that the Category 2 and Category 4 deficiencies were found as noted on the Summary of Cited Deficiencies by Area.

The finding of a Category 2 deficiency initiates the Unresolved Issue process of the ISSC. You are afforded 30 calendar days from the date of this letter to respond to this office. FDA will advise you in writing within 30 calendar days of your written response if it is acceptable and resolves the deficiencies. If you do not respond, your response is found to be unacceptable, or if you disagree with the trip report findings, FDA will notify the Commissioner of the Department of Marine Resources that FDA considers the matter to be an Unresolved Issue.

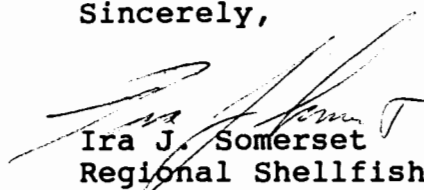
The finding of a Category 4 deficiency requires that you submit an action plan to this office within 30 calendar days detailing how and when you will achieve compliance, and how you will demonstrate that you have achieved compliance. Corrections should be made as soon as possible.

Deficiencies not corrected by the action plan will be treated as Category 2 deficiencies.

Within 30 calendar days of your written response, FDA will advise you in writing if your action plan is acceptable to resolve the deficiencies. If you do not respond, your response is found the unacceptable, or if you disagree with the trip report findings, FDA will then treat the deficiency as a Category 2 deficiency for Unresolved Issue action by the Interstate Shellfish Sanitation Conference.

The Category B deficiencies should be addressed in the process of correcting the Category 2 and Category 4 deficiencies. Please do not hesitate to contact me if you have any questions.

Sincerely,



Ira J. Somerset
Regional Shellfish Specialist

Enclosure - Trip Report

pc: Field, HFR-NE24
SPIB, HFR-628 w/enclosure
Brands, HFC-152 w/enclosure
P. Anderson w/enclosure
W. Foster w/enclosure



Memorandum

Date April 13, 1994
From Regional Shellfish Specialist
Northeast Region
Subject Trip Report
To Maine Files - Focus '94

I. Purpose and Time Period

A review of the growing area survey and classification program element was conducted between February 15 and March 22. This evaluation was conducted in accordance with the protocol and procedures of Focus '94.

II. Scope

There are 45 designated growing areas in Maine, six of which were classified prohibited at the time of this evaluation. Twenty-five were evaluated using Worksheet B (100% Growing Area) and 14 were evaluated using Worksheet C (Statistical Sample).

III. Persons Contacted

Lamoine Laboratory: Paul Anderson
Boothbay Harbor Laboratory: Walter Foster, Stuart
Sherborn, Jan Barter, Fran Pierce, Laura Livingston.

IV. Findings

Copies of the worksheets are attached, as is a compilation by growing area of cited deficiencies. There were 16 Category 2 deficiencies, 32 Category 4 deficiencies, and 20 B-category deficiencies.

V. State Action

During the evaluations, there was discussion of each deficiency and why it did not meet the requirements. Mr. Anderson, Mr. Foster and staff members took notes and discussed means to effect corrections and bring the program into compliance with the Focus '94 criteria.

VI. State Accomplishments

The program staff has been coping with the effects of the severe budget restrictions imposed on the state employees: reduced work week (to 37.5 hours); state shut-down days (5/year); unpaid time off (up to 22 days/year last year, but reduced to 14 days this year); and the "bumping" of trained, experienced employees by others with no program experience due to the personnel system. As the situation has been stabilized in the last year or so, the staff in Boothbay has begun to build their confidence and knowledge levels, and their skills.

There has been a considerable amount of work expended by the Lamoine Lab staff to insure that the deficiencies noted in the 1991 100% growing area evaluation were addressed and that procedures were developed to assure that they were not repeated. To that end, several quality control procedures and checks have been instituted.

VII. Recommendations

All of the following recommendations were discussed with program managers:

- A. Plan for and schedule the triennial reevaluations.
- B. Because of the large number of areas and their extent, begin planning and scheduling resurveys so they will not all be due at once.
- C. Develop consistency in reporting and evaluation procedures and methods. This includes formats, instructions, field procedures, reporting procedures, training, quality control and administrative oversight.
- D. Review the existing sanitary surveys to assure that they meet the requirements of the NSSP to justify the classification assigned to the area and present a comprehensive and persuasive argument that the classification is correct.


Ira J. Somerset

Attachments (Worksheets, Summary)

Summary of Cited Deficiencies by Area

<u>Area</u>	<u>Manual Cite</u>	<u>Question #</u>	<u>Objectionable Condition</u>	<u>Enforcement Level</u>
Area A	C.6.a	(2)	There is no management plan.	B
Area H	C.2.C	(1a)	No sanitary survey prior to upgrade.	2
		(1b)	No written analysis of data.	2
	C.1.d.i(b)	(1) (1b)	Stations 1-3 did not have 5 samples per station per year.	4
	C.1.d.ii	(1-5) (6)	No triennial revaluation. Area not closed.	4 4
Area J	C.5.a	(1)	No written sanitary survey or justification.	2
	C.5.a (C.1.a)	(2)	The survey was not completed for the Harraseeket River Restricted Area prior to allowing harvesting.	2
	C.5.a (C.1.a)	(3)	No info in files.	B
	C.2.e	(1)	Although there is no sanitary survey, the restricted area is not closed.	2
Area M	C.1.c	(2b,2c,2d)	The sanitary survey report does not include evaluation of meteorological, hydrographic or geographic characteristics.	4
		(2f)	Stations 9 and 21 has less than 15 samples.	4
	C.1.b.i	(14)	No summary of shoreline survey findings.	B
	C.4.a	(1)	Data were not evaluated to demonstrate rain runoff effects or response of area to runoff.	2
	C.1.a	(1)	Sanitary survey not dated, not complete	2
		(2)	Harvesting allowed without sanitary survey being completed.	2
	C.2.e	(1)	Conditional area is available for harvest without completed survey.	2
Area N	C.1.b.iii(a)	(1)	Based on agreement with Regional Office areas were classified with less than 15 samples/sta. in 1988.	4
	C.2.c	(1a)	Upgrade documents do not meet sanitary survey requirements.	4
		(2a)	Area reopened without documentation to show original classification was met	2
	C.4.a	(1)	No analysis presented to demonstrate conditional area meets approved area criteria when open.	2

<u>Area</u>	<u>Manual Cite</u>	<u>Question #</u>	<u>Questionable Condition</u>	<u>Enforcement Level</u>
	C.1.c	(2f)	Agreement with R/O allowed classification with less than 15 samples per station in 1988. (see C1.b.iii(a)).	2
	C.1.d.ii	(1-5)	No triennial reevaluation.	4
		(6)	Area remains open; no action taken.	4
Area R	C.1.d.ii	(1-5)	No Triennial reevaluation.	4
		(6)	Area remains open; no action taken	4
Area T	C.1.b.i	(14)	No summary of shoreline survey.	B
Area U	C.1.b.ii	(1a)	No evaluation of meteorological effects.	4
		(1b)	No evaluation of hydrographic effects.	4
	C.1.b.i	(14)	No shoreline survey summary.	B
	C.1.c	(2b)	No narrative analysis of meteorological	4
		(2c)	or hydrographic effects in sanitary survey.	
Area Y	C.1.b.i	(14)	No summary of the shoreline survey.	B
	C.1.C	(1)	No narrative analysis of findings.	4
		(2c)	No data evaluation	4
	C.1.d.ii	(1-5)	No triennial reevaluation.	4
		(6)	Area remains open; no action taken.	4
Area Z	C.1.b.i	(12)	Birds/wild animals not evaluated	B
Area EA	C.1.c	(2c,d)	Sanitary survey report does not include evaluation of hydrographic and geographic characteristics.	4
	C.4.a	(1)	Report does not demonstrate that it meets approved area criteria when open.	2
Area EB	C.1.b.i	(8a,b)	Sources noted, flows estimated but determination of direct/indirect not made.	B
	C.1.b.i	(10)	Older reports did not specifically address animal farms. Newer portions do.	2
	C.1.b.i	(15)	Older ones do not use Appendix B format, newer ones do.	B
Area EC	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
Area ED	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
	C.1.b.i	(12)	Wild animals noted but not evaluated.	B

<u>Area</u>	<u>Manual Cite</u>	<u>Question #</u>	<u>Objectionable Condition</u>	<u>Enforcement Level</u>
Area EE	C.1.c	(2d)	Effects of geographic characteristics not evaluated.	4
		(2e)	No analysis of bacteriological results.	4
		(2g)	No analysis of data.	4
Area EG	C.1.c	(2b,c,d)	No evaluation of meteorological, hydrographic or geographic effects.	4
	C.1.1.ii	(1-3)	No triennial reevaluation.	4
Area EH	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
Area EI	C.1.b.ii	(1a-c)	Meteorological, hydrographic and geographic effects mentioned but not evaluated in older surveys. They are in newer surveys.	4
	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
Area EJ	C.1.c	(2b)	No discussion of meteorological effects.	4
		(2d)	No discussion of geographic effects.	4
	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
Area EK	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
	C.1.d.ii	(1-5)	No triennial reevaluation.	4
		(6)	Area not closed.	4
Area EL	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
	C.4.a	(3)	Management plan factors not predictable for 2-month Turner Cove opening.	B
Area EM	C.1.d.ii	(1-5)	No triennial reevaluation.	4
		(6)	Area not closed.	4
Area EN	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
Area EQ	C.1.b.i	(8a,b)	Direct/indirect determination not made.	B
	C.1.d.ii	(1-5)	No triennial reevaluation.	4
		(6)	Area not closed.	4
Area ER	C.1.b.i	(a)	Pollution sources not located on map.	2